

BETH C. DRAIN, CA CSR NO. 7152

BEFORE THE
INDEPENDENT CITIZENS' OVERSIGHT COMMITTEE AND THE
APPLICATION REVIEW SUBCOMMITTEE
TO THE
CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE
ORGANIZED PURSUANT TO THE
CALIFORNIA STEM CELL RESEARCH AND CURES ACT
EMERGENCY MEETING

LOCATION: VIA ZOOM

DATE: JUNE 12, 2020
11 A.M.

REPORTER: BETH C. DRAIN, CA CSR
CSR. NO. 7152

FILE NO.: 2020-12

BETH C. DRAIN, CA CSR NO. 7152

I N D E X

ITEM DESCRIPTION NO.	PAGE
OPEN SESSION:	
1. CALL TO ORDER.	3
2. ROLL CALL.	3
ACTION ITEMS:	
3. CONSIDERATION OF EXISTENCE OF EMERGENCY SITUATION. "EMERGENCY SITUATION" MEANS ANY OF THE FOLLOWING, AS DETERMINED BY A MAJORITY OF THE MEMBERS OF THE INDEPENDENT CITIZENS OVERSIGHT COMMITTEE: (A) WORK STOPPAGE OR OTHER ACTIVITY THAT SEVERELY IMPAIRS PUBLIC HEALTH OR SAFETY OR BOTH; (B) CRIPPLING DISASTER THAT SEVERELY IMPAIRS PUBLIC HEALTH OR SAFETY, OR BOTH.	4
4. CONSIDERATION OF APPLICATIONS SUBMITTED IN RESPONSE TO SPECIAL CALL FOR COVID-19 PROJECTS.	6
CLOSED SESSION:	
NONE	
5. DISCUSSION OF CONFIDENTIAL INTELLECTUAL PROPERTY OR WORK PRODUCT, PREPUBLICATION DATA, FINANCIAL INFORMATION, CONFIDENTIAL SCIENTIFIC RESEARCH OR DATA, AND OTHER PROPRIETARY INFORMATION RELATING TO APPLICATIONS SUBMITTED IN RESPONSE TO AGENDA ITEM "4" ABOVE. (HEALTH & SAFETY CODE 125290.30(F) (3) (B) AND (C)).	
DISCUSSION ITEMS:	
6. PUBLIC COMMENT.	NONE
7. ADJOURNMENT.	26

BETH C. DRAIN, CA CSR NO. 7152

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JUNE 12, 2020; 11 A.M.

CHAIRMAN THOMAS: THANK YOU, MARIA. I THINK WE CAN CERTAINLY HAVE THIS DISCUSSION FOR A VERY LONG TIME. WE SHALL NOW PROCEED INTO OUR FOURTH EMERGENCY MEETING OF THE ICOC AND THE APPLICATION REVIEW SUBCOMMITTEE DEALING WITH THE AWARDS FOR COVID-RELATED RESEARCH. MARIA, WILL YOU PLEASE CALL THE ROLL.

MS. BONNEVILLE: ANNE-MARIE DULIEGE.

DR. DULIEGE: HERE.

MS. BONNEVILLE: YSABEL DURON.

MS. DURON: HERE.

MS. BONNEVILLE: DAVID HIGGINS.

DR. HIGGINS: HERE.

MS. BONNEVILLE: STEVE JUELSGAARD.

MR. JUELSGAARD: HERE.

MS. BONNEVILLE: DAVE MARTIN. LAUREN MILLER. YOU ARE ON MUTE. NO. OKAY. ADRIANA PADILLA.

DR. PADILLA: HERE.

MS. BONNEVILLE: JOE PANETTA.

MR. PANETTA: HERE.

MS. BONNEVILLE: FRANCISCO PRIETO. ROBERT QUINT.

BETH C. DRAIN, CA CSR NO. 7152

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DR. QUINT: HERE.

MS. BONNEVILLE: AL ROWLETT.

MR. ROWLETT: HERE.

MS. BONNEVILLE: JEFF SHEEHY.

MR. SHEEHY: HERE.

MS. BONNEVILLE: OS STEWARD. I SEE YOU,
BUT I CAN'T HEAR YOU. YOU'RE ON MUTE.

DR. STEWARD: I'M HERE ON BOTH PHONE
AND --

MS. BONNEVILLE: I CAN HEAR YOU. YOU
SOUND GOOD.

DR. STEWARD: I'M GOING TO HAVE A PROBLEM
WITH MY PHONE WHICH I'M GOING TO HAVE TO USE. SO
YOU GUYS ARE GOING TO HAVE TO CALL ME AGAIN. FOR
WHATEVER REASON IT DOESN'T WORK ON THE PHONE.

MS. BONNEVILLE: JONATHAN THOMAS.

CHAIRMAN THOMAS: HERE.

MS. BONNEVILLE: ART TORRES.

MR. TORRES: HERE.

MS. BONNEVILLE: DIANE WINOKUR. PRESENT.
THANK YOU.

CHAIRMAN THOMAS: THANK YOU, MARIA.

SO FIRST ACTION ITEM IS, AS HAS BEEN THE
CASE WITH EACH OF THESE MEETINGS, CONSIDERATION OF
EXISTENCE OF EMERGENCY SITUATION. EMERGENCY

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1 SITUATION MEANS ANY OF THE FOLLOWING AS DETERMINED
2 BY A MAJORITY OF THE MEMBERS OF THE ICOC: A, WORK
3 STOPPAGE OR OTHER ACTIVITY THAT SEVERELY IMPAIRS
4 PUBLIC HEALTH OR SAFETY OR BOTH; B, CRIPPLING
5 DISASTER THAT SEVERELY IMPAIRS PUBLIC HEALTH OR
6 SAFETY OR BOTH. DO I HAVE A MOTION TO APPROVE?

7 DR. HIGGINS: SO MOVED.

8 DR. STEWARD: SO MOVED.

9 CHAIRMAN THOMAS: SO MOVED BY, I THINK, OS
10 AND SECONDED BY DAVID OR THE OTHER WAY AROUND.
11 MARIA, WILL YOU PLEASE CALL THE ROLL.

12 MS. BONNEVILLE: ANNE-MARIE DULIEGE.

13 DR. DULIEGE: YES.

14 MS. BONNEVILLE: YSABEL DURON.

15 MS. DURON: YES.

16 MS. BONNEVILLE: DAVID HIGGINS.

17 DR. HIGGINS: YES.

18 MS. BONNEVILLE: STEVE JUELSGAARD.

19 MR. JUELSGAARD: YES.

20 MS. BONNEVILLE: DAVE MARTIN. I THINK
21 DAVID IS ON BUT WE CAN'T HEAR HIM. LET ME SEE IF WE
22 CAN SEE HIM. CAN'T SEE HIM EITHER.

23 LAUREN MILLER.

24 ADRIANA PADILLA.

25 DR. PADILLA: YES.

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1 MS. BONNEVILLE: JOE PANETTA.
2 MR. PANETTA: YES.
3 MS. BONNEVILLE: FRANCISCO PRIETO. ROBERT
4 QUINT.
5 DR. QUINT: YES.
6 MS. BONNEVILLE: AL ROWLETT.
7 MR. ROWLETT: YES.
8 MS. BONNEVILLE: JEFF SHEEHY.
9 MR. SHEEHY: YES.
10 MS. BONNEVILLE: OS STEWARD. YES?
11 JONATHAN THOMAS.
12 CHAIRMAN THOMAS: YES.
13 MS. BONNEVILLE: ART TORRES.
14 MR. TORRES: AYE.
15 MS. BONNEVILLE: DIANE WINOKUR.
16 MS. WINOKUR: YES.
17 MS. BONNEVILLE: THANK YOU.
18 CHAIRMAN THOMAS: THANK YOU VERY MUCH.
19 SO WE HAD ANOTHER VERY ROBUST DISCUSSION OF THE GWG
20 THIS TUESDAY WHICH FEATURED SOME SURPRISES,
21 INCLUDING MARK NOBLE WHO HAD COMPOSED AN ORIGINAL
22 SONG AND SANG IT TO THE GWG, WHICH WAS QUITE
23 SOMETHING.
24 IN ANY EVENT, WE'RE GOING TO PROCEED TO
25 ITEM NO. 4, CONSIDERATION OF APPLICATIONS SUBMITTED

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1 IN RESPONSE TO SPECIAL CALL FOR COVID-19 PROJECTS.

2 TURN THE MEETING OVER AT THIS POINT TO MR. SHEEHY.

3 MR. SHEEHY: THANK YOU J.T.

4 DR. SAMBRANO, ARE YOU GOING TO LEAD US
5 THROUGH A DISCUSSION ON THE ROUND?

6 DR. SAMBRANO: YES, MR. SHEEHY.

7 MR. SHEEHY: THANKS, GIL.

8 DR. SAMBRANO: DOUG, COULD YOU PUT UP THE
9 SLIDE DECK PLEASE?

10 SO A LOT OF WHAT I'M GOING TO REVIEW
11 INITIALLY IS JUST AGAIN THE BACKGROUND ON THIS
12 PROGRAM. AS YOU KNOW, WE ISSUED THE CALL FOR
13 COVID-19. AND WHEN WE STARTED -- THIS WILL BE THE
14 LAST CYCLE IN WHICH WE USE OUR PARTNERING
15 OPPORTUNITIES FROM DISCOVERY TO CLIN2 BECAUSE, AS
16 YOU KNOW, IN THE PREVIOUS BOARD MEETING WE EXPANDED
17 IT TO INCLUDE DISC1 AND MADE SOME OTHER CHANGES. SO
18 THIS STILL FOLLOWS THE SLIGHTLY OLDER PROGRAM
19 ANNOUNCEMENTS. AND \$5 MILLION WAS SET ASIDE IN
20 ORDER TO SUPPORT IT. NEXT SLIDE PLEASE.

21 SO A REMINDER OF THE PROGRAMS THAT ARE
22 COVERED IN THIS CYCLE. WE HAPPEN TO HAVE A LOT OF
23 DISCOVERY APPLICATIONS THAT CAME IN. WE ALSO HAD
24 ONE TRANSLATIONAL CLINICAL TRIAL THAT WERE REVIEWED.
25 THE MAXIMUM AWARD AMOUNTS FOR THESE, WHICH ARE

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1 MODEST, ARE SHOWN AS WELL AS THE APPROXIMATE AWARD
2 DURATION FOR THESE.

3 NEXT SLIDE PLEASE. ALSO, AS YOU KNOW, WE
4 HAVE, BECAUSE OF THE URGENCY OF THIS PROGRAM,
5 INCLUDED A REQUIREMENT THAT ALL PROPOSALS ACHIEVE A
6 CLEAR DELIVERABLE WITHIN SIX MONTHS. SO DEPENDING
7 ON THE TYPE OF PROGRAM, THOSE ARE SHOWN HERE.

8 SO IN TOTAL WE ENDED UP WITH TEN
9 APPLICATIONS THAT WERE REVIEWED THIS CYCLE. AS I
10 MENTIONED, ONE CLIN2, ONE TRAN, AND THE REST OF THEM
11 DISCOVERY. NEXT SLIDE PLEASE.

12 SO THE OUTCOME AND THE RECOMMENDATIONS
13 FROM THE GRANTS WORKING GROUP ARE AS FOLLOWS: THERE
14 WERE TWO APPLICATIONS, ONE TRAN AND ONE DISC, THAT
15 FELL INTO THE RECOMMENDED FOR FUNDING RANGE. AND SO
16 THE TOTAL APPLICANT REQUESTS FOR THOSE TWO
17 APPLICATIONS IS ABOUT 500,000. AND THE FUNDS
18 AVAILABLE OR REMAINING IN THE PROGRAM ARE ABOUT 2.5
19 MILLION.

20 SO THE NEXT SLIDE PLEASE. THE FIRST
21 APPLICATION THAT WAS RECOMMENDED IS TRAN1-11975. SO
22 THIS AN APPLICATION THAT RECEIVED A SCORE OF 85.
23 AND SO THE GOAL OF THIS APPLICATION IS TO TEST A
24 SMALL MOLECULE DRUG CANDIDATE, WHICH IS BERZOSERTIB.
25 AND SO THIS SMALL MOLECULE THAT HAS THE POTENTIAL TO

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1 BLOCK A CRITICAL STEP IN VIRAL REPLICATION AND
2 POTENTIALLY BLOCK VIRAL GROWTH AND ULTIMATELY IN
3 THIS WAY PROTECTING LUNG PROGENITOR CELLS. AND SO
4 THAT'S THE TRAN1 PROJECT.

5 THERE'S A DISCOVERY PROJECT, 11838. AND
6 SO THAT ONE IS DEVELOPING QUITE A UNIQUE VACCINE
7 BIOLOGIC. THE GOAL OF THIS ONE IS TO CREATE AN
8 ARTIFICIAL ANTIGEN PRESENTING CELL. SO THIS IS A
9 BIOMATERIAL PLATFORM ESSENTIALLY, AND IT HAS SEVERAL
10 COMPONENTS TO IT THAT TOGETHER, WHEN INTRODUCED INTO
11 A PATIENT, WOULD HELP INDUCE T-MEMORY STEM CELLS TO
12 BOOST THE IMMUNE SYSTEM AGAINST SARS COV2. AND THIS
13 MAY BE PARTICULARLY HELPFUL IN THE ELDERLY
14 POPULATION WHERE THAT FUNCTION IS NOT AS WELL
15 DEVELOPED.

16 SO THOSE ARE THE TWO PROPOSALS. AND,
17 DOUG, IF YOU COULD PUT UP THE SPREADSHEET, WE CAN
18 SHOW THE REMAINING APPLICATIONS THAT WERE REVIEWED
19 AND THEIR RESPECTIVE SCORES. MR. SHEEHY, THAT END
20 OF MY PRESENTATION.

21 MR. SHEEHY: THANK YOU, DR. SAMBRANO.

22 SO COULD I GET A MOTION TO MOVE ANY OF THE
23 APPLICATIONS IN THE UNFUNDABLE RANGE INTO THE
24 FUNDABLE RANGE, IF THERE'S A DESIRE TO DO SO?
25 HEARING NONE, COULD I GET A MOTION TO NOT FUND THE

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1 APPLICATIONS IN THE UNFUNDABLE CATEGORY, AND THEN
2 WE'LL JUST DEAL WITH THE TWO IN THE FUNDABLE RANGE.

3 DR. DULIEGE: SO MOVED.

4 MR. ROWLETT: SECOND.

5 MR. SHEEHY: MOVED BY MS. DURON, IS THAT
6 CORRECT, AND THE SECOND --

7 DR. DULIEGE: ANNE-MARIE.

8 MR. SHEEHY: AND THE SECOND WAS FROM?

9 MR. ROWLETT: AL ROWLETT.

10 MR. SHEEHY: AL ROWLETT. THANK YOU, AL.
11 IS THERE ANY BOARD COMMENT? ANY PUBLIC COMMENT?

12 MS. BONNEVILLE: DOUG, CAN YOU LET ME KNOW
13 IF YOU SEE ANY HANDS?

14 MR. GUILLEN: NO HANDS.

15 MR. SHEEHY: COULD YOU CALL THE ROLL
16 PLEASE, MS. BONNEVILLE.

17 MS. BONNEVILLE: ANNE-MARIE DULIEGE.

18 DR. DULIEGE: YES.

19 MS. BONNEVILLE: YSABEL DURON.

20 MS. DURON: YES.

21 MS. BONNEVILLE: DAVID HIGGINS.

22 DR. HIGGINS: YES.

23 MS. BONNEVILLE: STEVE JUELSGAARD.

24 MR. JUELSGAARD: YES.

25 MS. BONNEVILLE: DAVE MARTIN. DAVE,

BETH C. DRAIN, CA CSR NO. 7152

1 YOU'RE ON. CAN I SEE YOU? HOLD ON. I THINK I SAW
2 YOU. DAVE. THUMBS UP. OKAY. THANK YOU.

3 MS. MILLER: I JUST CAME BACK.
4 UNFORTUNATELY I DON'T KNOW WHAT WE'RE VOTING ABOUT.
5 SO UNFORTUNATELY I THINK YOU'RE GOING TO HAVE TO --

6 MS. BONNEVILLE: OKAY. NO PROBLEM.

7 ADRIANA PADILLA.

8 DR. PADILLA: YES.

9 MS. BONNEVILLE: JOE PANETTA.

10 MR. PANETTA: YES.

11 MS. BONNEVILLE: FRANCISCO PRIETO. ROBERT
12 QUINT.

13 DR. QUINT: YES.

14 MS. BONNEVILLE: AL ROWLETT.

15 MR. ROWLETT: YES.

16 MS. BONNEVILLE: JEFF SHEEHY.

17 MR. SHEEHY: YES.

18 MS. BONNEVILLE: JONATHAN THOMAS.

19 CHAIRMAN THOMAS: YES.

20 MS. BONNEVILLE: ART TORRES.

21 MR. TORRES: AYE.

22 MS. BONNEVILLE: DIANE WINOKUR.

23 MS. WINOKUR: YES.

24 MS. BONNEVILLE: MOTION CARRIES.

25 MR. SHEEHY: THANK YOU.

BETH C. DRAIN, CA CSR NO. 7152

1 NOW I THINK WE'LL START WITH THE ONE THAT
2 SCORED HIGHEST. DO I HAVE A MOTION TO EITHER FUND
3 OR NOT FUND DISC19-11838, THE BIOMATERIAL VACCINE TO
4 ENHANCE THE FORMATION OF SARS COV2 SPECIFIC T-MEMORY
5 STEM CELLS?

6 CHAIRMAN THOMAS: SO MOVED.

7 DR. DURON: I'D LIKE TO MAKE A COMMENT.

8 MR. SHEEHY: SURE. YSABEL, MAYBE WE CAN
9 GET A MOTION ON THE TABLE. CHAIRMAN THOMAS, WAS
10 THAT A MOTION TO APPROVE?

11 CHAIRMAN THOMAS: YES.

12 MR. SHEEHY: DO I HAVE A SECOND FOR THAT?

13 DR. DULIEGE: I SECOND.

14 MR. SHEEHY: GREAT. THANK YOU. MS.
15 DURON.

16 MS. DURON: THE RESEARCH GROUP SENT IN
17 COMMENTS ABOUT PLANS FOR OUTREACH TO THE UNDERSERVED
18 COMMUNITIES, WHICH I APPRECIATE, BUT I DON'T THINK
19 IT GOES FAR ENOUGH. AND I DON'T KNOW IF WE CAN SAY
20 SOMETHING ABOUT THIS, HAVE A SIDE VOTE ON THIS,
21 AMEND OUR AMENDMENTS ABOUT THIS, BUT I WOULD LIKE TO
22 SEE AN ACTUAL MORE FIRM DATA PRESENTED BY THESE TO
23 SHOW EXACTLY WHAT THEY'RE DOING IN TERMS OF WORKING
24 IN THESE UNDERSERVED COMMUNITIES. I HAVE SEEN OVER
25 AND OVER WHERE WE ARE TOLD THEY'LL ENSURE DIVERSITY.

BETH C. DRAIN, CA CSR NO. 7152

1 TO ME THAT DOESN'T GO FAR ENOUGH. YOU MIGHT PUT ONE
2 OR TWO PEOPLE OF COLOR IN IT AND FROM DIFFERENT
3 ORGANIZATION AND YOU CALL THAT DIVERSITY. THEY
4 MEANWHILE SAY OUR FINDINGS SHOW THAT OUR COMMUNITY
5 AND OUR APPROACH OFFER THE POSSIBILITY TO ADDRESS
6 UNDERSERVED COMMUNITIES AND UNDERREPRESENTED
7 MINORITIES. POSSIBILITY FOR ME IS NOT GOOD ENOUGH.

8 GIVEN THAT YOU LOOK AT THE DEATH RATES --
9 AND THEY PROPOSE TO DO THIS IN ORDER TO ADDRESS
10 ISSUES FOR ELDERLY AND THOSE MOST IMPACTED. IF YOU
11 LOOK AT THE DEATH RATES, THIS COMES OUT OF THE UCLA,
12 THE CENTER FOR THE STUDY OF LATINO HEALTH AND
13 CULTURE, THAT DID A STRATIFICATION BY RACE,
14 ETHNICITY, AND AGE FOR PEOPLE OVER THE AGE OF 65.
15 NON-HISPANIC WHITES DEATH RATE WAS 10.4, FOR
16 HISPANIC IT WAS 18.6, FOR BLACK NON-HISPANIC IT WAS
17 31.3, AND FOR ASIAN NON-HISPANIC 16.4.

18 FOR THOSE BETWEEN THE AGES OF 50 AND 64,
19 FOR WHITE NON-HISPANIC IT WAS 1.4 AND FOR HISPANICS
20 IT WAS 3.5. THEY DIDN'T HAVE ENOUGH DATA ON BLACK
21 AND ASIAN COMMUNITIES TO PUT IT HERE. OBVIOUSLY IT
22 IS THE MINORITY RACIAL AND ETHNIC GROUPS WHO ARE
23 MOST HEAVILY IMPACTED.

24 SO I WOULD LIKE TO SEE, WHEN THESE PLANS
25 ARE REVIEWED, WHEN THEY HAVE PROPOSALS, THAT THEY

BETH C. DRAIN, CA CSR NO. 7152

1 SHOW US VERY SPECIFICALLY THE PROPORTIONATE NUMBER
2 THAT THEY WILL BE INCLUDING IN THEIR DESIGNED PLANS
3 THAT THE REVIEWERS CAN SEE AND CAN RECOGNIZE THAT
4 THEY'RE NOW GOING TO GET PAST POSSIBILITY AND THAT,
5 IN FACT, THEY'RE LOOKING AT VERY SPECIFICALLY, AND I
6 THINK THESE COMMUNITIES ACTUALLY HAVE TO BE
7 OVERSAMPLED IN ORDER FOR US TO GET TO A PLACE WHERE
8 THERE'S EQUITY IN CARE, IN TESTING, IN VACCINES, ET
9 CETERA, FOR THESE POPULATIONS WHO ARE OBVIOUSLY THE
10 ONES MOST UNDER ATTACK BY THIS VIRUS.

11 AND SO I WOULD LIKE IT -- ONCE AGAIN, I
12 DON'T KNOW IF IT'S AN AMENDMENT, HELP ME HERE, OR IF
13 IT'S NOTES OR IF IT BECOMES PART OF THE CODIFICATION
14 OF OUR RFP'S, BUT SAYING THAT YOU WILL LOOK, TRY TO
15 BE DIVERSE IS GOOD ENOUGH FOR ME. AND I HOPE THAT
16 OTHERS OF YOU UNDERSTAND WHY GIVEN THE DATA THAT I
17 JUST PRESENTED. THANK YOU, JEFF.

18 MR. SHEEHY: THANK YOU, MS. DURON.

19 I WONDER, DR. SAMBRANO, AND ALSO, FRANKLY,
20 EVEN MEMBERS OF THE BOARD MIGHT HAVE A WAY IN WHICH
21 WE CAN PERHAPS OFFER SOME LANGUAGE TO NAIL DOWN WHAT
22 MS. DURON IS TALKING ABOUT. I DID READ THE
23 STATEMENT FROM THE APPLICANT, BUT OBVIOUSLY I'M NOT
24 WELL VERSED ENOUGH IN THIS TO BE ABLE TO PUT
25 TOGETHER SOMETHING THAT ACTUALLY CAPTURES WHAT MS.

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1 DURON IS ASKING. COULD WE GET SOME HELP PERHAPS?

2 MR. TORRES: I DON'T THINK WE NEED A BOARD
3 LANGUAGE. I THINK MORE WE NEED IS FOR YSABEL TO
4 COME UP WITH THE LANGUAGE THAT SHE FEELS COMFORTABLE
5 WITH, GET TO GILBERT, AND THEN GILBERT HAS A
6 CONVERSATION WITH THE GRANTEES ACROSS THE BOARD.

7 WE'VE ALREADY SET IN MOTION BEFORE THAT WE
8 AGREE WITH THE DURON AMENDMENT. IT'S NOW A MATTER
9 OF PUTTING IT SOMEWHAT IN WRITING AND THEN LET
10 GILBERT NEGOTIATE WITH THE GRANTEES THAT THIS IS
11 WHAT WE EXPECT.

12 MR. SHEEHY: SENATOR TORRES, I THINK THAT
13 THAT IS A GREAT IDEA, BUT I THINK, PER THE SPECIFIC
14 APPLICATION, THERE IS A DISCUSSION OF HLA TYPES.
15 AND THERE HAS BEEN SOME -- THERE WAS A PAPER
16 PUBLISHED, AND WE HAD THIS DISCUSSION ON OUR PRIOR
17 VACCINE CANDIDATE, THAT THE HLA TYPES THAT YOU USE
18 IN DEVELOPING YOUR VACCINE NEED TO BE APPROPRIATE TO
19 THE EPIDEMIOLOGY OF THE EPIDEMIC THAT WE ARE SEEING.

20 MR. TORRES: RIGHT.

21 MR. SHEEHY: AND IT'S UNCLEAR TO ME, WHEN
22 I READ THIS STATEMENT, AND I THINK THAT'S WHAT MS.
23 DURON IS ALLUDING TO, HOW SUCCESSFULLY THE APPLICANT
24 ADDRESSES THAT ISSUE. AND I THINK THAT'S PERHAPS
25 WHERE WE ARE LOOKING FOR SOME CLARITY TO MAKE SURE

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1 THAT MATCH WITH THE DATA THAT MS. DURON HAS
2 PRESENTED THAT SHOWS THAT THE EPIDEMIOLOGY FOR THIS
3 PANDEMIC DOES -- IS DISPARATE AND IMPACT ON
4 DIFFERENT RACIAL GROUPS, THAT THAT'S REFLECTED IN
5 THE MODELS THAT THEY TEST THIS VACCINE IN.

6 MR. TORRES: RIGHT. I THINK THAT'S THE
7 INFORMATION I SENT HER FROM -- I THINK SO. IS THAT
8 THE SAME INFORMATION I SEN YOU FROM PROFESSOR --

9 DR. DURON: YES.

10 MR. TORRES: SO MAYBE WHY DON'T I TURN
11 AROUND AND GET TOGETHER WITH DAVID AND THEN COME
12 BACK WITH SOME LANGUAGE THAT YOU CAN LOOK AT,
13 YSABEL, AND WE GO FROM THERE?

14 DR. DURON: I APPRECIATE THAT. THANK YOU.
15 I APPRECIATED THAT GIL SAID THAT REVIEWERS WERE TO
16 INCLUDE THIS AS PART OF THEIR LOOKING AT SCORING.
17 AND I DON'T KNOW IF THAT GOT TO THEM ON TIME. BUT I
18 WOULD LIKE TO SEE THAT AS PART OF THE SCORING METHOD
19 WHEN WE GET THAT ONE SHEET. I WOULD LIKE TO SEE
20 THAT THEY'VE ACTUALLY TAKEN A LOOK AT THE
21 PROPORTIONATE ENGAGEMENT AND INCLUSION OF THESE
22 UNDERSERVED COMMUNITIES SO THAT WE CAN SEE THAT THEY
23 ACTUALLY TOOK A LOOK AT THAT PIECE AND THAT THEY
24 RECOGNIZED THAT IT HAD A LOW OR A HIGH SCORE AND
25 THAT IT WAS BEING THOUGHTFULLY DONE. SO CAN WE GET

BETH C. DRAIN, CA CSR NO. 7152

1 THAT IN THERE TOO?

2 MR. TORRES: WE CAN GET ANYTHING YOU WANT
3 IN THERE.

4 DR. SAMBRANO: I JUST WANTED TO CLARIFY.
5 SO WE HAVE PUT A REQUIREMENT IN FOR ALL CLINICAL
6 TRIAL PROPOSALS THAT THEY MUST INCLUDE A CLEAR PLAN
7 OF OUTREACH AND HOW THEY'RE GOING TO INCLUDE
8 PATIENTS FROM UNDERSERVED COMMUNITIES THAT ARE
9 DISPROPORTIONATELY AFFECTED.

10 NOW, FOR THE REMAINDER OF THE TYPES OF
11 APPLICATIONS WE GET, FOR EXAMPLE, THIS IS A
12 DISCOVERY APPLICATION, ALTHOUGH I THINK MANY OF THE
13 REVIEWERS HAVE THIS IN MIND AND ARE ACTUALLY
14 VIGILANT OF THE FACT THAT COVID-19 IMPACTS ON
15 UNDERSERVED POPULATIONS AND THEY HAVE INCLUDED IT IN
16 THEIR REVIEW, IT HAS NOT BEEN A SPECIFIC REQUIREMENT
17 FOR APPLICANTS TO INCLUDE THAT IN THEIR APPLICATION.

18 HOWEVER, AS WE DID WITH THE LAST
19 APPLICATION IN THE LAST CYCLE, WE ASKED AN APPLICANT
20 TO INCLUDE A SUPPLEMENT THAT WOULD BROADEN THE HLA
21 SUBTYPES THAT THEY INCLUDED IN THEIR STUDIES. WE
22 COULD DO THE SAME THING HERE AS AN APPROACH TO TRY
23 TO REMEDY THAT. BUT WE HAVE NOT YET INCLUDED THIS
24 AS A BROAD REQUIREMENT ACROSS ALL APPLICATIONS.

25 MR. TORRES: IF I MAY, WE HAD A SIMILAR

BETH C. DRAIN, CA CSR NO. 7152

1 PROBLEM AS I THINK I CITED EARLIER WITH SOME OF OUR
2 CLINICAL TRIALS THAT DIDN'T HAVE NATIVE AMERICANS
3 WITHIN THEIR TRIAL. NOW WE'RE SEEING THE NAVAJO
4 NATION, WE'RE SEEING OTHER RESERVATIONS IN
5 CALIFORNIA THAT I'M AWARE OF FOR THE PROPENSITY OF
6 INFECTION RATE IS VERY, VERY HIGH. WE NEED TO BE
7 CAREFUL ON MAKING SURE THAT GO BEYOND THE HLA
8 DESIGNATION BECAUSE THAT REALLY ONLY INCLUDES ASIAN
9 AND WHITE FOLKS, DOESN'T INCLUDE ANYBODY ELSE.

10 MS. BONNEVILLE: I THINK OS HAD A COMMENT.

11 MR. SHEEHY: I SAW THAT.

12 DR. STEWARD: THANK YOU. SO THIS IS
13 COMPLICATED. AND IT REALLY REFLECTS IMPORTANTLY ON
14 TWO COMPETING CONSIDERATIONS HERE. ONE IS THE VERY
15 IMPORTANT CONSIDERATION THAT YSABEL RAISED AND WE'VE
16 BEEN DISCUSSING ABOUT THE IMPORTANCE OF MAKING OUR
17 THERAPIES AVAILABLE BROADLY ACROSS THE GROUPS WHO
18 NEED THOSE THERAPIES. AT THE SAME TIME WE ARE
19 TALKING HERE ABOUT EARLY STAGE GRANTS THAT DON'T
20 HAVE A LOT OF MONEY. AND ACTUALLY IT'S FINE TO HAVE
21 THESE REQUIREMENTS IN CLINICAL TRIALS BECAUSE
22 BASICALLY YOU'RE TALKING ABOUT INVOLVEMENT OF
23 PEOPLE.

24 THE PROBLEM HERE IS FEASIBILITY. YOU HAVE
25 AN APPROACH HERE THAT IS PROPOSING TO DO X, AND THEY

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1 HAVE DONE THIS BASED ON THE HLA FOCUS THAT IS MOST
2 AVAILABLE, SHALL WE SAY, THE FASTEST, AND THE MOST
3 SCIENTIFICALLY VALID AT THIS POINT. YOU CAN'T JUST
4 EXPAND THE PROJECT INTO DOMAINS BEYOND THE
5 FEASIBILITY AND NOT IMPACT ON THE PROBABILITY OF
6 SUCCESS.

7 EVERYBODY LOOKS AT THESE GRANT
8 APPLICATIONS AS CAN THEY ACTUALLY DO THIS. AND IF
9 THEY'RE PROPOSING IT TOO MUCH, THE ANSWER IS NO.
10 WHAT WE ARE LOOKING FOR HERE IS RAPID PROGRESS IN A
11 SIX-MONTH TIME FRAME AND THE EXPECTATION THAT THAT
12 IS GOING TO LEAD TO THE SECOND STAGE OF FUNDING.
13 AND CAN'T ASK THEM TO JUST DO EVERYTHING ALL AT ONCE
14 HERE.

15 SO I JUST WILL SAY THAT THIS IS NOT
16 SOMETHING THAT WE CAN SOLVE BY JUST IMPOSING SOME
17 KIND OF A REQUIREMENT ON THE GRANTEE. WE CAN'T HAVE
18 GIL SOLVE THIS BY SAYING, OH, YOU HAVE TO DO ALL
19 THIS BECAUSE THEY CAN'T WITH THE MONEY THAT WE ARE
20 GIVING THEM. HONESTLY, WE EITHER NEED TO DISAPPROVE
21 IT AND ASK THEM TO COME BACK, OR WE NEED TO APPROVE
22 IT WITH A STRONG MESSAGE THAT WE WOULD LIKE TO SEE
23 THAT, BUT I DON'T THINK WE CAN IMPOSE ANY
24 CONTINGENCIES AT THIS POINT. THANK YOU VERY MUCH.
25 I'M SORRY THAT WAS A LONG COMMENT.

BETH C. DRAIN, CA CSR NO. 7152

1 MR. SHEEHY: THANK YOU, DR. STEWARD.

2 I UNDERSTAND THE APPLICANT IS ON THE LINE.
3 MAYBE WE CAN HEAR FROM THE APPLICANT AND GET SOME
4 CLARIFICATION ON THE STATEMENT THAT THE APPLICANT
5 SENT AND HOW THEY ARE ADDRESSING THE ISSUE. I DON'T
6 KNOW IF THAT IS DR. LEE OR SOMEONE ELSE. IS THE
7 APPLICANT ON THE LINE?

8 MS. BONNEVILLE: MY UNDERSTANDING IS THAT
9 THE APPLICANT IS ON THE LINE. DOUG, DO YOU SEE --

10 MR. GUILLEN: IF YOU ARE ON THE PHONE,
11 PLEASE DIAL STAR NINE TO RAISE YOUR HAND AND WE WILL
12 UNMUTE YOUR LINE FOR COMMENTS.

13 MR. SHEEHY: WE WEREN'T REALLY GOING TO
14 PUBLIC -- I THOUGHT THE APPLICANT WAS ON THE LINE.

15 MR. GUILLEN: APPLICANT IS ON THE LINE.

16 MS. BONNEVILLE: THAT'S WHAT I THOUGHT.

17 MR. SHEEHY: PLEASE. COULD YOU --

18 DR. LEE: THIS IS DR. SONG LEE FROM
19 BIOENGINEERING AT UCLA. I APPRECIATE THE COMMENTS
20 FOR THIS DISCOVERY APPLICATION. WE WERE NOT
21 REQUIRED TO INCLUDE OUTREACH ACTIVITIES. AND I
22 THINK AFTER WE GOT THE SCORE, I WAS RECOMMENDED TO
23 ADD THE SUPPLEMENT ALTHOUGH IT'S REQUIRED FOR THE
24 TRANS GRANTS. AND THIS IS FOR LOOKING I THINK
25 PREPARE US FOR THE NEXT PHASE OF STUDIES.

BETH C. DRAIN, CA CSR NO. 7152

1 IN THE CURRENT DISCOVERY GRANT, WE HAVE
2 153 BUDGET. WE PLAN TO DIVIDE THE PROJECT, AND THEN
3 WE'LL DO A SMALL SAMPLE FOR HUMAN SAMPLES. SO I
4 THINK I WILL DEFINITELY INCLUDE -- THE STATEMENT IS
5 TO SHOW THAT WE CAN ACCESS TO ALL OF THESE SAMPLES
6 WITH DIVERSE RACE, GENDER, ET CETERA. SO I THINK
7 THIS STATEMENT WAS SERVE AS A GUIDELINE FOR THIS
8 PHASE, SMALL SAMPLE STUDY AND ALSO FOR THE NEXT
9 PHASE. WE HOPE TO BE ABLE TO REACH.

10 I THINK, IF APPROPRIATE, WE COULD GET IT
11 APPROVED AND WE MOVE ON TO PROVE THE FEASIBILITY AS
12 WE JUST DISCUSSED. AND AFTERWARDS WE ARE GOING TO
13 FOCUS ON THE LARGER SCALE CLINICAL SAMPLE STUDIES.

14 MR. SHEEHY: THANK YOU, DR. LEE. DOES
15 THAT KIND OF ANSWER FOLKS' QUESTIONS?

16 DR. DURON: MAY I SAY SOMETHING?

17 MR. SHEEHY: PLEASE.

18 MS. DURON: I APPRECIATE WHAT DR. LEE HAS
19 TO SAY, AND I ALSO APPRECIATE WHAT OS HAS TO SAY
20 BECAUSE THAT IS ONE OF THE REASONS WHY I'VE SAID
21 FROM THE VERY BEGINNING WHEN I RAISED THIS ISSUE WAS
22 THAT WHEREVER APPROPRIATE THROUGHOUT ANY OF THE
23 RFP'S THAT WE PUT OUT THAT THIS BE PART AND PARCEL
24 OF THE RFP. SO THAT IT'S NOT AN, OH, YOU ASKED ME
25 TO DO THIS NOW WHEN IT WASN'T IN THE RFP. I THINK

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1 I'LL GO BACK TO WHAT ART SAID. MAYBE WE CAN LOOK AT
2 THIS, TALK ABOUT THIS SOME MORE, AND BRING IT BACK
3 TO THE BOARD FOR FULL CONSIDERATION BECAUSE I KNOW
4 IT'S NOT THE TIME TO HAVE THAT, BUT I DO APPRECIATE
5 WHAT DR. LEE IS SAYING, BUT I'M THINKING THAT'S
6 BECAUSE WE ARE NOT BEING CLEAR, OUT FRONT, AND
7 REALLY GETTING ALL THIS JUST AS A MATTER OF COURSE
8 IN OUR RFP'S ACROSS THE BOARD. AND I'M HOPING WE'LL
9 BE AROUND LONG ENOUGH TO BE ABLE TO DO THAT IN THE
10 FUTURE. SO THANK YOU VERY MUCH, DR. LEE. THANKS,
11 ART, AND THANKS, JEFF. I APPRECIATE IT.

12 MR. SHEEHY: YOU BET.

13 DO WE HAVE FURTHER BOARD COMMENT ABOUT
14 THIS APPLICATION? DO WE HAVE ADDITIONAL PUBLIC
15 COMMENT?

16 SO WE HAVE A MOTION TO FUND THIS
17 APPLICATION. COULD WE CALL THE ROLL ON THIS PLEASE,
18 MS. BONNEVILLE.

19 MS. BONNEVILLE: ANNE-MARIE DULIEGE.

20 DR. DULIEGE: YES.

21 MS. BONNEVILLE: YSABEL DURON.

22 MS. DURON: YES.

23 MS. BONNEVILLE: DAVID HIGGINS.

24 DR. HIGGINS: YES.

25 MS. BONNEVILLE: STEVE JUELSGAARD.

BETH C. DRAIN, CA CSR NO. 7152

1 MR. JUELSGAARD: YES.
2 MS. BONNEVILLE: DAVE MARTIN. YES.
3 THUMBS UP. OKAY.
4 LAUREN MILLER. ADRIANA PADILLA.
5 DR. PADILLA: YES.
6 MS. BONNEVILLE: JOE PANETTA.
7 MR. PANETTA: YES.
8 MS. BONNEVILLE: FRANCISCO PRIETO. ROBERT
9 QUINT.
10 DR. QUINT: YES.
11 MS. BONNEVILLE: AL ROWLETT.
12 MR. ROWLETT: YES.
13 MS. BONNEVILLE: JEFF SHEEHY.
14 MR. SHEEHY: YES.
15 MS. BONNEVILLE: OS STEWARD.
16 DR. STEWARD: YES.
17 MS. BONNEVILLE: JONATHAN THOMAS.
18 CHAIRMAN THOMAS: YES.
19 MS. BONNEVILLE: ART TORRES.
20 MR. TORRES: AYE.
21 MS. BONNEVILLE: DIANE WINOKUR.
22 MS. WINOKUR: YES.
23 MS. BONNEVILLE: THANK YOU. THE MOTION
24 CARRIES.
25 MR. SHEEHY: WE HAVE ONE REMAINING

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1 APPLICATION. CAN I GET A MOTION EITHER TO APPROVE
2 THIS APPLICATION FOR FUNDING OR TO NOT APPROVE IT
3 FOR FUNDING?

4 DR. HIGGINS: APPROVE FOR FUNDING. MOVE.

5 MR. SHEEHY: GREAT. DO I HAVE A SECOND?

6 MR. PANETTA: SECOND.

7 MR. SHEEHY: GREAT. DO WE HAVE ANY BOARD
8 DISCUSSION AROUND THIS APPLICATION? IS THERE ANY
9 PUBLIC COMMENT AROUND THIS APPLICATION? COULD WE
10 CALL THE ROLL THEN PLEASE. THE MOTION IS TO APPROVE
11 THIS APPLICATION 11975.

12 MS. BONNEVILLE: ANNE-MARIE DULIEGE.

13 DR. DULIEGE: YES.

14 MS. BONNEVILLE: YSABEL DURON.

15 MS. DURON: YES.

16 MS. BONNEVILLE: DAVID HIGGINS.

17 DR. HIGGINS: YES.

18 MS. BONNEVILLE: STEVE JUELSGAARD.

19 MR. JUELSGAARD: YES.

20 MS. BONNEVILLE: DAVE MARTIN. YES.

21 LAUREN MILLER. ADRIANA PADILLA.

22 DR. PADILLA: YES.

23 MS. BONNEVILLE: JOE PANETTA.

24 MR. PANETTA: YES.

25 MS. BONNEVILLE: FRANCISCO PRIETO. ROBERT

BETH C. DRAIN, CA CSR NO. 7152

1 QUINT.
2 DR. QUINT: YES.
3 MS. BONNEVILLE: AL ROWLETT.
4 MR. ROWLETT: YES.
5 MS. BONNEVILLE: JEFF SHEEHY.
6 MR. SHEEHY: YES.
7 MS. BONNEVILLE: OS STEWARD.
8 DR. STEWARD: YES.
9 MS. BONNEVILLE: JONATHAN THOMAS.
10 CHAIRMAN THOMAS: YES.
11 MS. BONNEVILLE: ART TORRES.
12 MR. TORRES: AYE.
13 MS. BONNEVILLE: DIANE WINOKUR.
14 MS. WINOKUR: YES.
15 MS. BONNEVILLE: THE MOTION CARRIES.
16 MR. SHEEHY: THANK YOU, MS. BONNEVILLE.
17 CHAIRMAN THOMAS, THIS COMPLETES THE
18 BUSINESS OF THE APPLICATION REVIEW SUBCOMMITTEE.
19 CHAIRMAN THOMAS: THANK YOU VERY MUCH, MR.
20 SHEEHY.
21 THAT, I BELIEVE, MAKES PROJECTS 10 AND 11
22 THAT THE BOARD HAS NOW FUNDED IN THIS COVID ROUND.
23 WE WILL HAVE MORE TO ENTERTAIN PRESUMABLY IN TWO
24 WEEKS. THANK YOU ALL FOR YOUR DISCUSSION AS ALWAYS.
25 WE ARE NOW AT THE PUBLIC COMMENT PORTION

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1 OF THE MEETING. DOES ANYBODY ON THE PHONE WISH TO
2 MAKE A COMMENT ON ANY MATTER WHATSOEVER? HEARING
3 NONE, THAT CONCLUDES TODAY'S EMERGENCY MEETING.
4 THANK YOU ALL VERY MUCH.

5 MS. BONNEVILLE: REALLY QUICKLY. OUR NEXT
6 BOARD MEETING IS JUNE 26TH. IT'S A FULL BOARD
7 MEETING, AND IT WILL BE A FEW HOURS. SO SETTLE INTO
8 YOUR COMFY SEATS ON ZOOM.

9 MS. DURON: WHAT TIME, MARIA?

10 MS. BONNEVILLE: I BELIEVE WE'LL START
11 AROUND 9:00 OR 9:30. I HAVEN'T CONFIRMED WITH J.T.
12 AND MARIA YET. I'LL FOLLOW UP WITH YOU GUYS ON THAT
13 TIMING AND WE'LL SEND SOMETHING OUT BY MONDAY.

14 MR. TORRES: THOSE BOARD MEMBERS WHO WANT
15 TO COME IN EARLIER.

16 MS. DURON: I MAY COME IN LATER. THAT'S
17 WHY I ASKED.

18 MS. BONNEVILLE: SOME EARLY. SOME LATE.
19 I'M GOING TO WIN SOME, I'M GOING TO LOSE SOME. I
20 DON'T KNOW. I DON'T KNOW WHAT TO DO. TOO MANY OF
21 YOU.

22 (THE MEETING WAS THEN CONCLUDED AT 11:39 A.M.)
23
24
25

REPORTER'S CERTIFICATE

I, BETH C. DRAIN, A CERTIFIED SHORTHAND REPORTER IN AND FOR THE STATE OF CALIFORNIA, HEREBY CERTIFY THAT THE FOREGOING TRANSCRIPT OF THE ZOOM PROCEEDINGS BEFORE THE INDEPENDENT CITIZEN'S OVERSIGHT COMMITTEE AND THE APPLICATION REVIEW SUBCOMMITTEE OF THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE IN THE MATTER OF ITS EMERGENCY MEETING HELD ON JUNE 12, 2020, WAS HELD AS HEREIN APPEARS AND THAT THIS IS THE ORIGINAL TRANSCRIPT THEREOF AND THAT THE STATEMENTS THAT APPEAR IN THIS TRANSCRIPT WERE REPORTED STENOGRAPHICALLY BY ME AND TRANSCRIBED BY ME. I ALSO CERTIFY THAT THIS TRANSCRIPT IS A TRUE AND ACCURATE RECORD OF THE PROCEEDING.

BETH C. DRAIN, CA CSR 7152
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